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CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 8 October 2003 with an application for Letters Patent number 528800 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 8 November 2004.

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528800

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PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

"Headgear for Masks"

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We, **FISHER & PAYKEL HEALTHCARE LIMITED**, a company duly incorporated under the laws of New Zealand of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

FIELD OF INVENTION

This invention relates to patient or user interfaces particularly though not solely for use in delivering artificial respiration therapy to patients requiring respiratory humidification treatment. In particular the present invention relates to a mask with improved headgear.

BACKGROUND OF THE INVENTION

In the art of respiration devices, there are well known variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the user's face such that gas may be provided at positive pressure within the mask for consumption by the user. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

One requisite of such respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear such a mask continuously for hours or perhaps even days. In such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

In common with prior art designs, is an inability to attach the plenum, supplying gases to the user, to the head strap such that the position of the plenum may be altered without distorting the position of the mask on the user's face.

US Patent No. 6,347,631 and US Patent No. 6,516,802 are examples of prior art that provide a means of rigidly attaching a gas plenum to the hear gear which utilises a cantilever adjustment mechanism. The cantilever adjustment mechanism provides a means of adjusting the headgear and any movement of the gas plenum is achieved by sliding the plenum through a plurality of rings on the cantilever arrangement.

SUMMARY OF THE INVENTION

It is an object of the present invention to attempt to provide an interface and headgear which goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

Accordingly in a first aspect the present invention may broadly be said to consist in a device for delivering a supply of gases to a user comprising or including:

an interface including a hollow body, a gases inlet and a sealing member configured to in use rest against the face of a user, adapted in use to supply gases to said user,

a conduit supplying said gases to said interface, said conduit attached to an inlet to said hollow body, and

headgear adapted to attach to said interface and around the head of said user,

where said conduit is affixed to said headgear such that any load is taken by said headgear and not said interface when a force is placed on said conduit .

Preferably there exists a sliding connection between said headgear and said interface when said interface is engaged with said user.

Preferably said hollow body has a forehead rest with harnessing slots to secure said hollow body to said headgear.

Preferably said conduit includes a first conduit connected to a second conduit that attaches to the inlet of said interface.

Preferably said second conduit is more flexible than said second conduit.

Preferably said headgear has a plurality of hook and loop attachments.

Preferably said second tubing is attached to said headgear by said hook and loop attachments.

Preferably said second tubing is mechanically attached to said headgear.

Preferably said headgear includes a transverse strap which in use lies on top of said user's head.

Preferably said transverse strap includes at least one of said hook and loop attachments.

Preferably said transverse strap is connected said forehead rest by a telescopic extension mechanism.

Preferably said transverse strap is connected said forehead rest by an adjustable glider mechanism.

Preferably said headgear includes a mechanical clip attachment point.

Preferably said headgear includes a double locking mechanical clip attachment point.

Preferably said headgear means includes a lateral strap which in use lies across the top of said user's head.

Preferably said lateral strap includes said hook and loop attachment.

Preferably said interface and said headgear are interconnected by a looped glider engaging mechanism.

Preferably said headgear is a single strap adapted to in attach around the midline of

said user's head.

Preferably said sliding connection is attached to said headgear and adapted to in use connect around said flexible tube friction fit connector when said flexible tube is substantially vertical.

Preferably said headgear has a mesh sling adapted to in use connect around the connection between said first conduit and said second conduit.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred forms of the present invention will now be described with reference to the accompanying drawings.

Figure 1 is a block diagram of a humidified continuous positive airway pressure (CPAP system) as might be used in conjunction with the interface of the present invention.

Figure 2 is an illustration of a first embodiment of the interface of the present invention where slideable hook and loop attachments are provided to attach the gases conduit to the interface headgear.

Figure 3 is a second embodiment of the interface of the present invention.

Figure 4 is an illustration of a contoured connector adapted to connect a first conduit with a second conduit, these conduits supplying gases to the interface.

Figure 5 is an illustration of a third embodiment of the interface of the present invention, where a telescopic extension is provided between the headgear and interface.

Figure 6 is an illustration of a forth embodiment of the interface of the present invention, where a vertical glider mechanism is provided between the headgear and interface.

Figure 7 is an illustration of a fifth embodiment of the interface of the present invention, where an additional support strap is provided between the headgear and gases conduit.

Figure 8 an illustration of a sixth embodiment of the interface of the present invention, where an additional, but alternative, support strap is provided between the headgear and gases conduit.

Figure 9 is an illustration of a seventh embodiment of the interface of the present invention, where a looped gliding strap is provided between the headgear and interface and the gases conduit is fixed to a headgear strap by a hook and loop attachment.

Figure 10 is an illustration of an eighth embodiment of the interface of the present invention, where the gases conduit is threaded through a loop configuration formed on one of the headgear straps.

Figure 11 is an illustration of an ninth embodiment of the interface of the present invention, where the gases conduit is threaded through an alternative loop configuration formed on one of the headgear straps.

Figure 12 is an illustration of a tenth embodiment of the interface of the present invention, where the gases conduit is restrained by a number of sliding straps.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides improvements in the delivery of respiratory therapy. In particular an interface is described which is comfortable for the user to wear and significantly reduces the movement of the mask on the user's face as compared with the prior art. It will be appreciated that the interface as described in the preferred embodiment of the present invention can be used in respiratory care generally or with a ventilator but will now be described below with reference to use in a humidified Continuous Positive Airway Pressure (CPAP) system. It will also be appreciated that the present invention can be applied to nasal masks, oral masks, and combination nasal-oral masks.

With reference to Figure 1 a humidified CPAP system is shown in which a user or patient 1 is receiving humidified and pressurised gases through an interface 2 connected to a humidified gases transportation pathway or inspiratory conduit 3. It should be understood that delivery systems could also be VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. Inspiratory conduit 3 is connected to the outlet 4 of a humidification chamber 5 which contains a volume of water 6. Inspiratory conduit 3 may contain heating means or heater wires (not shown) which heat the walls of the conduit to reduce condensation of humidified gases within the conduit. Humidification chamber 6 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. Humidifier 8 is provided with control means or electronic controller 9 which may comprise a microprocessor based controller executing computer software commands stored in associated memory.

Controller 9 receives input from sources such as user input means or dial 10 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to user 1. The controller may also receive input from other sources, for example temperature and/or flow velocity sensors 11 and 12 through connector 13 and heater plate temperature sensor 14. In response to the user set humidity or temperature value input via dial 10 and the other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5. As the volume of water 6 within the humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface. The water vapour is then passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 which enters the chamber through inlet 16. Exhaled gases from the user's mouth are passed directly to ambient surroundings in Figure 1.

Blower 15 is provided with variable pressure regulating means or variable speed fan 21 which draws air or other gases through blower inlet 17. The speed of variable speed fan 21 is controlled by an electronic controller 18 (or alternatively the function of controller 18 could be carried out by controller 9) in response to inputs from the controller 9 and a user set predetermined required value (preset value) of pressure or the fan speed via dial 19.

Respiratory Mask

According to a first embodiment of the present invention the interface is shown in Figure 2 as a nasal-oral mask. It will be appreciated the interface could equally be a nasal mask, oral mask or nasal-oral mask. The mask 2 includes a hollow body 22, with an inlet 23 connected to a section of flexible tubing 24, and a mask cushion 30. The flexible tubing's free end 25 preferably has a friction fit connector 26 which mates with the inspiratory conduit 3, which supplies gases to the mask inlet 23. The other end of the flexible tubing is connected by known methods to the inlet 23 of the mask 2. As shown in Figure 2 an outlet bias vent part 28 is disposed between the other end 27 of the flexible tubing 24. The outlet vent part 28 allows gases expired by the user to be vented. The mask 2 is positioned on the face of the user 1 with headgear 29, including at least one strap secured around the back of the head of the user 1. The restraining force from the headgear 29 on the hollow body 22 ensures enough compressive force on the mask cushion 30 to provide an effective seal against the user's face.

The hollow body 22 is constructed of a relatively inflexible material for example, polycarbonate plastic. Such a material would provide the requisite rigidity as well as being

transparent and a relatively good insulator. The expiratory gases can be expelled through a valve (not shown) in the mask, a further expiratory conduit (not shown), or any other such method as is known in the art.

Forehead Rest

Referring to Figure 2, the mask 2 includes a bridge member 31 that is substantially I shaped and has the purpose of providing a forehead rest for the user. Harnessing slots 32 are provided at the top end of the bridge member 31 which receive and enable the securement of straps 33, 34 from the headgear 29 to secure the mask 2 to the headgear 29 and user's face. For the users comfort one or more resilient cushions 35 are provided on bridge member 31 to rest on the forehead of the user. The cushions 35 are constructed by injection moulding or extruding, from silicon or any other foam materials as is known in the art for providing cushioning. In other forms of the interface, such as that interface shown in Figures 5 and 6, the bridge member 56 may be a T-shaped forehead rest having cushions similar to that described above.

Mask Headgear

To ensure user comfort and effective pressure on the mask cushion, the headgear 29 may be constructed either using two straps running around the back of the user's head as shown in Figure 2 or with a wider single strap or any other configurations as are known in the art. For example, the headgear as shown in Figures 7 and 8 have headgear that comprises one strap that fits about the back of the user's head. In this case the single or double strap configurations would be constructed using neoprene but may also be constructed using any material as is known in the art that will be comfortable for the user.

Referring back to Figure 2, the headgear 29 is shown connected to the hollow body 22. Rather than the traditional fixed or adjustable attachments the present invention utilises a sliding strap 36 to attach the headgear to the hollow body 22. The strap 36 is preferably constructed of polyacetyl (Delrin 500P NC010) using injection moulding techniques to give a polished finish. This material, similar to other nylon based derivatives, with its polished finish has a particularly low friction co-efficient, and therefore slides with respect to the hollow body 22 with very little resistance. Such a sliding strap is described in our co-pending New Zealand application number 514184 and is herein included by way of reference.

The sliding strap 36 includes a mid-section 37 intended to reciprocate with the engaging clips 38, terminated at each end by loops 39 (of which only one of the two is shown in Figure 2) that attach to the headgear 29, for example by hook and loop material,

such as VELCRO™, straps.

The hollow body 22 includes at least two engaging clips 38 (of which only one is shown in Figure 2), where in use the sliding strap 36 snaps into the engaging clips 38 and can only be removed there from using substantial force. This means that with any normal use the sliding strap 36 will stay retained within the engaging clips 38. In other embodiments of the interface and headgear different numbers of clips may be provided in order to allow different headgear and sliding strap configurations, for example, see Figures 7 and 8 for alternative clip configurations.

In a further embodiment shown in Figure 9 the present invention is illustrated using a harness system to attach the mask hollow body to the headgear 29. This harness system comprises a loop 81 of low friction, tough, fatigue resistant cord (or extruded plastic) which engages the headgear 29 through hook and loop attachments 82, 83, 84, 85 to the mask 2 through the engaging clips 26 and slot 87 formed in the bridging member 88 of the mask forehead rest. This system provides for freedom of movement about three mutually perpendicular axes without breaking the seal between the mask cushion 30 and the user's face, and accommodates movement of the flexible tubing 24 and inspiratory conduit 3.

Flexible Tubing Extension Piece

In the preferred embodiment of the present invention a section of highly flexible tubing 24 is provided that attached to the inspiratory conduit 3 and mask inlet 23. In less preferred embodiments of the present invention the inspiratory conduit 3 connects directly to the mask inlet 23.

The flexible tubing 24 is configured to in use connect to the mask inlet 23 while the free end is attached to the inspiratory conduit 3. Therefore, the flexible tubing 24 accommodates movement of the inspiratory conduit 3 (the gases supply line) and movement of the user without affecting the efficiency of the mask seal as any loading on the tubing or conduit is transferred to the headgear. The flexible tubing 24 is preferably a spiral wound tube constructed of a plastics material, for example, polyethylene.

Flexible Tubing Stabilisation

A plurality of hook and loop material loops 26, 40, 43, 44 may be slideably attached to the headgear as illustrated in Figures 2 or 3 to which the connector, the flexible tubing or inspiratory conduit is securely held in position. A similar loop may alternatively be slideably located on headgear that is configured to include a transverse or lateral strap running over the top of the user's head so that the flexible tubing also runs over the top of the user's head. Figures 5 or 11 show an example of this.

Alternatively, Figure 3 shows the flexible tubing 24 connected to the hollow body inlet 23 and an upper headgear strap 46. Here a mechanical attachment, such as a contoured connector 44 as shown in Figure 4, that is permanently attached, for example, by being moulded about the end of the inspiratory conduit 3. The connector 44 may be attached to any one of the headgear straps 45, 46, 47 in use by fixing a corresponding sliding loop 43, 44, 45 about the recessed part 48 of the connector 44.

In Figure 3 as well as a lower sliding strap 49 an upper sliding strap 50 is provided to allow the user's more head movement without putting to much load on the mask, preventing the disruption of the seal between the mask and the user's face.

In a further embodiment shown in Figure 5, the mask and headgear has a telescopic extension mechanism 51 that is constructed in a minimum of two sections. The first section is an outer sheath 52 and the second section is a slideable inner sheath 53, which when not in use resides within the outer sheath 52. The inner sheath's upper end 54 is attached to the transverse headgear strap 41 and the outer sheath bottom end 55 is attached to the rear surface of the mask T-piece forehead rest 56. The transverse strap 42 has a loop 41 (similar to those described previously, but one which is preferably fixed) located on it and functions as a means of securing the connector 44 or merely the flexible tube 24 or inspiratory conduit 3 to the headgear strap 42. The telescopic extension mechanism 51 is constructed from a plastics material, such as acetyl, nylon or polycarbonate, or an elastic type material. The inner sheath 53 has at its upper end a full loop, or other similar fastening mechanism, for connection to the transverse headgear strap 42. Therefore, a degree of movement is allowed such that the position of the inspiratory conduit may be altered without affecting the position of the mask on the user and while maintaining a gas tight seal.

Another alternative embodiment is shown in Figure 6. Here a glider mechanism is provided with the mask and headgear. The glider mechanism 57 is preferably constructed of a hard plastics material, for example, acetyl, nylon or polycarbonate or the like material, and has wide outer ends 58, 59 interconnected by a thinner central portion 60. The glider mechanism 57 may have a plurality of serrations along its length that allow it to be locked in different positions. In other forms the glider mechanism 57 may be smooth to enable it to freely move through a slot 61 provided in the forehead rest 56. The wide lower outer end 59 is permanently connected through the slot 61 in the upper portion of the forehead rest 56. A small loop 62 is permanently retained below the wide upper outer end 58 on the central portion 60 of the glider mechanism 57 for in use connection to the transverse

headgear strap 42. The position of the transverse strap 42 and thus the placement of the flexible tubing 24 may be varied by raising the lower wide end 59 of the glider mechanism 57, moving it upwards such that the central portion of the glider moves through the forehead rest slot 61. When the glider mechanism 57 is lockable and when the correct adjustment has been made, the action of lowering the lower wide end 59 towards the user effectively prevents movement of the central glider portion 60 by locking the glider mechanism 57 to the slot 61 between adjacent serrations.

In yet another embodiment of the present invention as shown in Figures 7 and 8, the hollow body 22 of the mask 2 is connected to a single strap configured headgear 63 using a closed loop sliding strap 64. The hollow body 22 is shown having two sets of engaging clips 65, 66 which in use the closed loop sliding strap 64 snaps into place, into the both the upper 66 and lower 65 engaging clips and can only be removed by using a substantial force. This means that with any normal use the closed loop sliding strap 64 will stay retained within the engaging clips 65, 66. The closed loop sliding strap 64 is attached to the headgear by known means, one example is by a hook and loop material at the end of the strap 67, 68, but other appropriate fastening means may be used. A support strap 69, preferably made of elastic material, is preferably attached to the lower edge of the headgear 63. In other forms of the support strap 69, the strap could be made from a rigid material, such as acetyl, nylon or polycarbonate or other hard plastics materials. In use the support strap 69 attaches around the flexible tube connector 70 (for example, a connector similar to connector 44 as shown in Figure 4) which hangs in a vertical direction below the mask inlet 23. The strap 69 in use will provide support for the connector 70 and reduce the downward drag on the mask 2 by transferring any loading on the tubing or mask to the headgear.

Alternatively, as shown in Figure 8 the mask 2 may be connected to the different single strap configured headgear 71 using two separate sliding straps 72, 73. The upper sliding strap 72 includes a mid-section intended to reciprocate with the upper engaging clips 74, terminated at each end by full loops which attach to the upper straps 75, 76 of the headgear. The upper strap 72 is a single gliding strap. The lower sliding strap 73 is a looped sliding strap terminated at each end by single full loops which attach to the headgear lower straps 78, 79. In other forms the upper and lower straps 72, 73 may not have full loops that attach to the headgear straps but they may be a continuous strap that can pull completely through the headgear straps. The top part of the lower sliding strap 73 includes a mid-section intended to reciprocate with the engaging clips 77 and the bottom

part of the lower sliding strap 73. In use the lower sliding strap 73 attaches around the flexible tube connector 80 (again, similar to that connector of Figure 4) which hangs in a vertical direction below the inlet 23 to the mask. The bottom part of the lower sliding strap 73 in use provides support for the connector 80 and reduces the downward drag on the mask 2.

Figures 10 and 11 show further alternative forms of the interface and headgear of the present invention. Figure 10 shows a mask 2 and headgear 90 having an upper strap 91 with a loop 92 extending from its upper edge. The loop 92 is capable of receiving the flexible tubing 24 and inspiratory conduit 3, such that the tubing or conduit can be threaded through the loop, thereby restraining the tube and/or conduit.

Figure 11 shows a mask 2 and headgear 93 that has a similar loop to that of Figure 11. The headgear 93 has an additional strap 95 extending between each side of the upper strap 94 of the headgear 93. Included on the additional strap 95 is a loop 96 of material (for example a loop of similar material to the headgear is sown to the strap 95) that the flexible tubing 24 and inspiratory conduit 3 are threaded through to restrain them. In Figure 11 the flexible tubing 24 and inspiratory conduit 3 are shown disconnected, in use, the tubing and conduit would be connected after the tubing 24 is threaded through the loop 96.

Figure 12 shows a tenth embodiment of the interface 100 of the present invention including headgear. The mask 2 of this embodiment is similar to that of Figures 7 and 8 in that it does not have an I-piece of T-piece extending upward from the mask 2. The mask 2 has a connection extending out from the mask body 22 that connects to the flexible tubing 24. The mask body 22 has on its outer surface two lower engaging clips 105, 106 and one upper engaging clip 107. The upper engaging clip 107 receives a first sliding strap 101 and the lower engaging clips 105, 106 receive a second sliding strap 102. Each of the sliding straps 101, 102 are capable of sliding horizontally over the mask body 22 when either of the headgear straps 103, 104 pull on the straps 101, 102 (in a similar manner as described with reference to the abovementioned embodiments).

The headgear straps 103, 104 also have a supporting strap 108 connected between the left side headgear strap 103 and right side headgear strap 104. The supporting strap 108 is connected midway to a connector 109 that may be slideably or permanently attached to the flexible tubing. Figure 12 shows a slideable or moveable connector 109, but a connector similar to the flexible tube connector 70 of Figure 7 may be provided with this embodiment.

In use, if the flexible tubing 24 is loaded, pulled or pushed the forces on the tubing 24 are transferred to the supporting strap 108, to the headgear straps 103, 104 and sliding straps 101, 102. The mask 2 is prevented from being pulled from the user's face nor the seal of the mask 2 on the user's face disrupted. In fact, in most situations when the flexible tubing 24 is loaded, pulled or pushed, the mask 2 and mask body 22 are caused by tightening of the sliding straps 101, 102 to be moved towards the user's face (that is, pulled tighter to the user's face).

In the embodiments of the mask and headgear described above the restraining of the flexible tubing 24 and inspiratory conduit 3 reduces movement of the mask 2 and breaking of the seal between the mask 2 and the user's face, when a force or load is placed on the flexible tubing 24 or inspiratory conduit 3. Further, in most cases any loading placed on the flexible tubing 24 or inspiratory conduit 3 is transferred to the sliding straps and headgear and not to the mask.

DATED THIS 8th DAY OF October 2003
AJ PARK
PER N Chelley
AGENTS FOR THE APPLICANT

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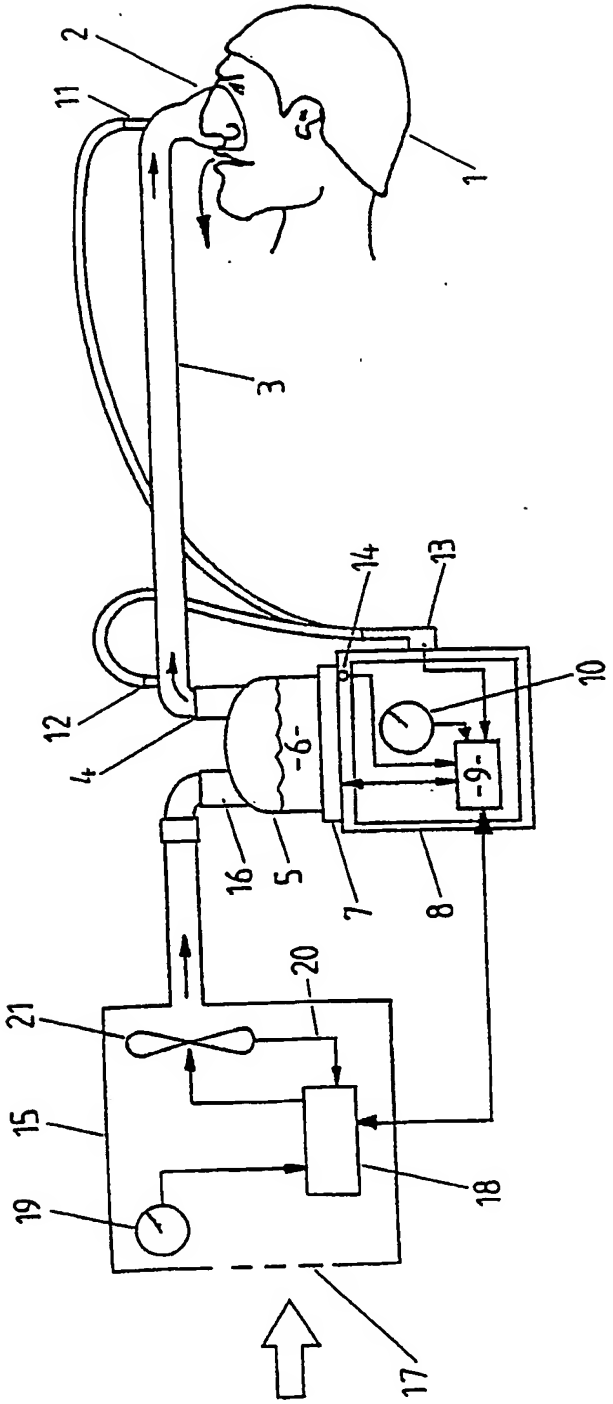

Figure 1

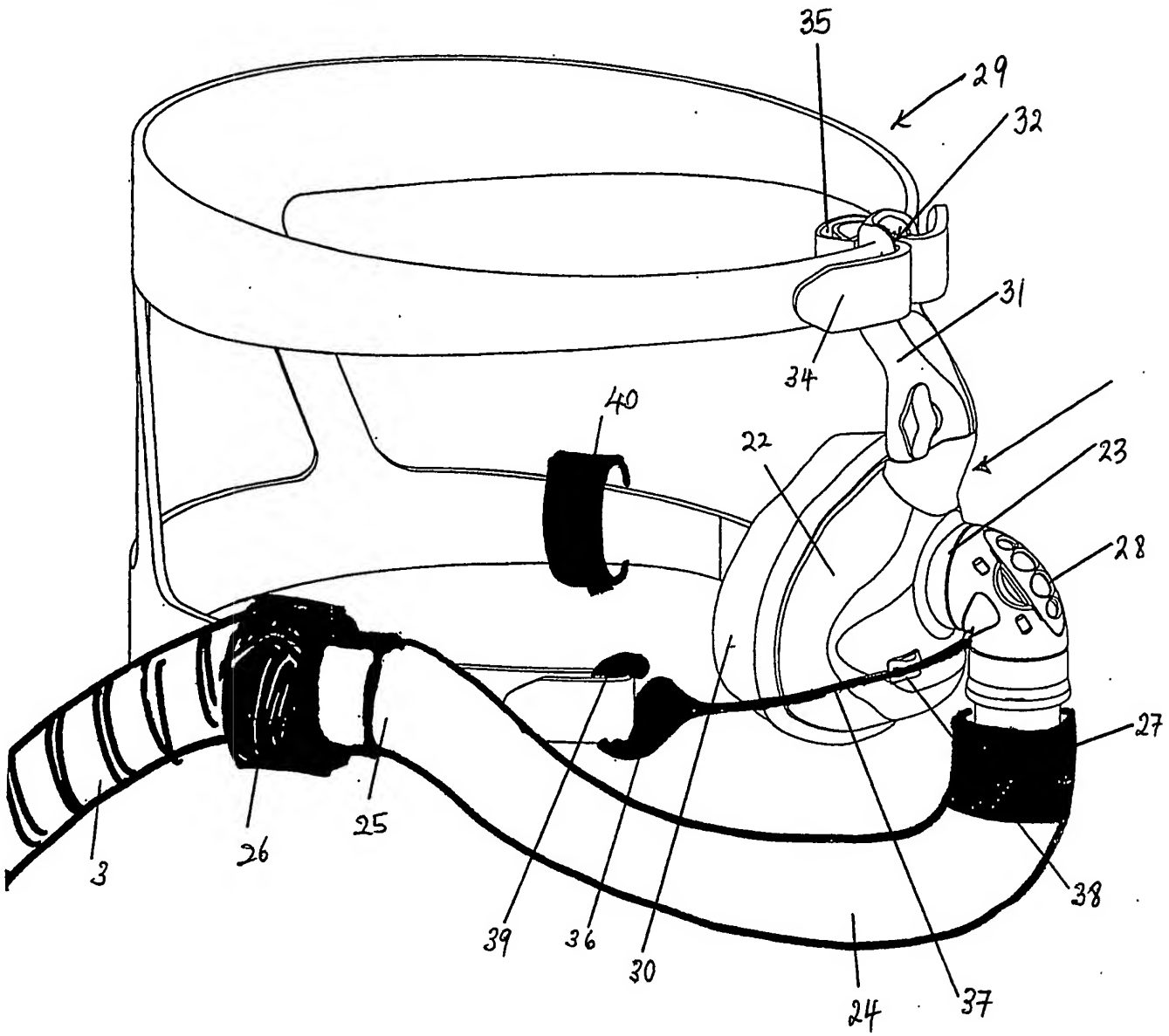

Figure 2

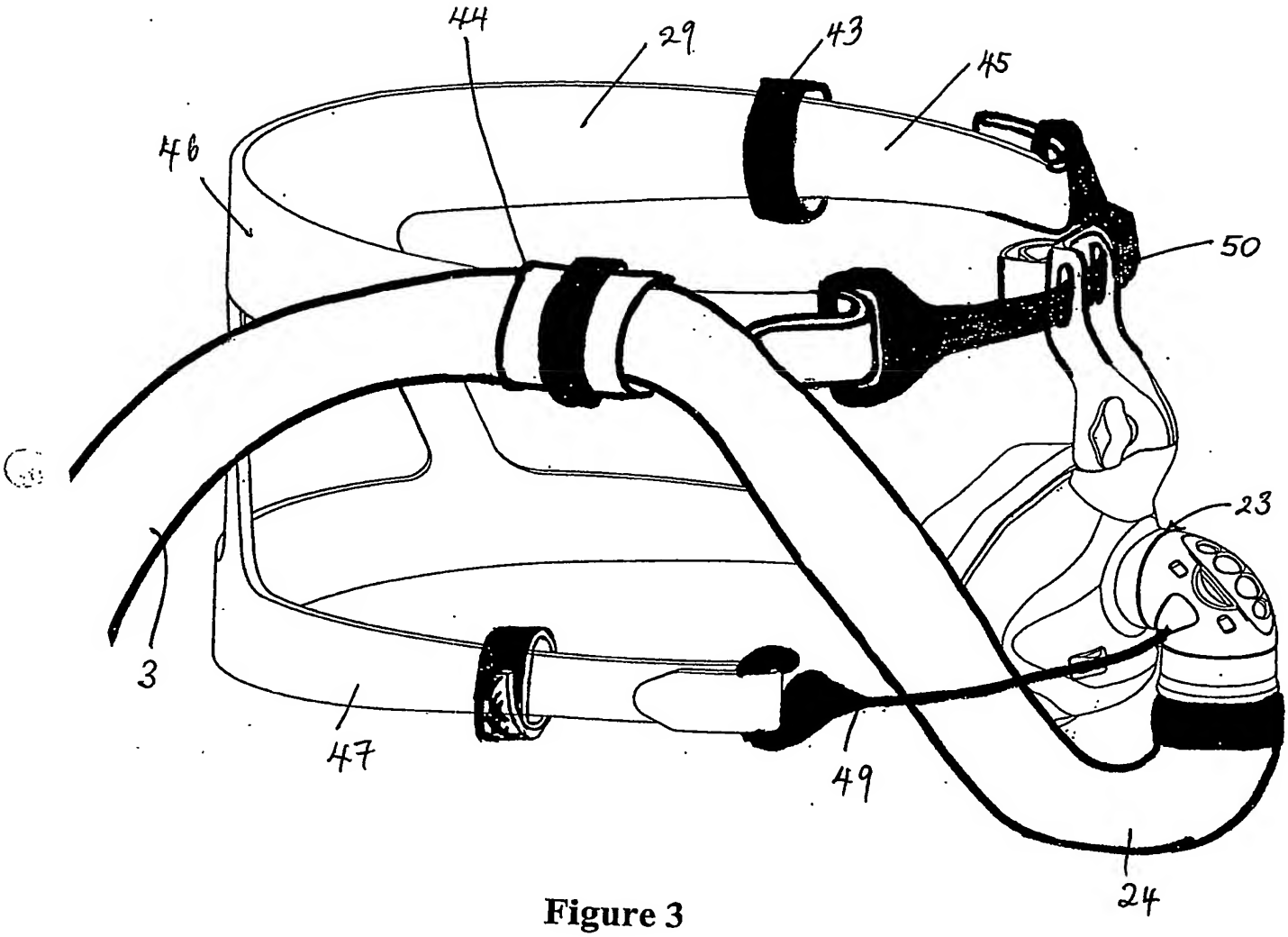

Figure 3

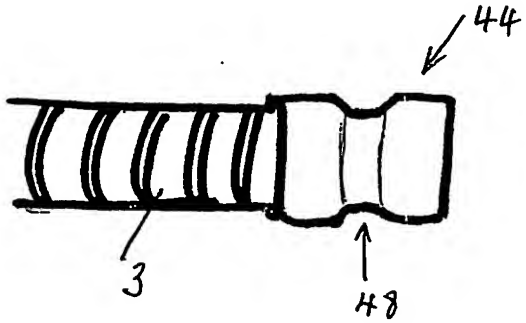

Figure 4

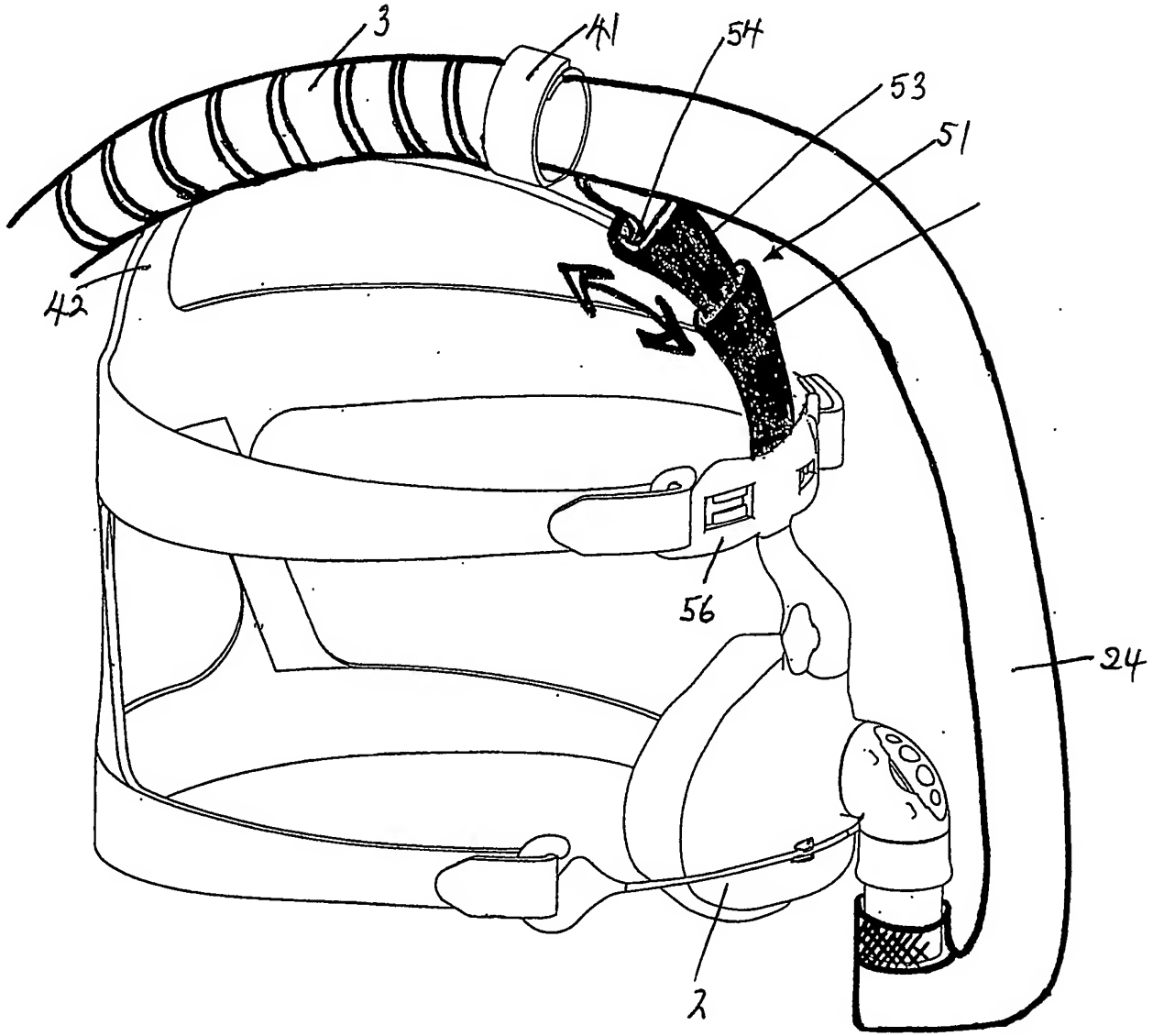

Figure 5

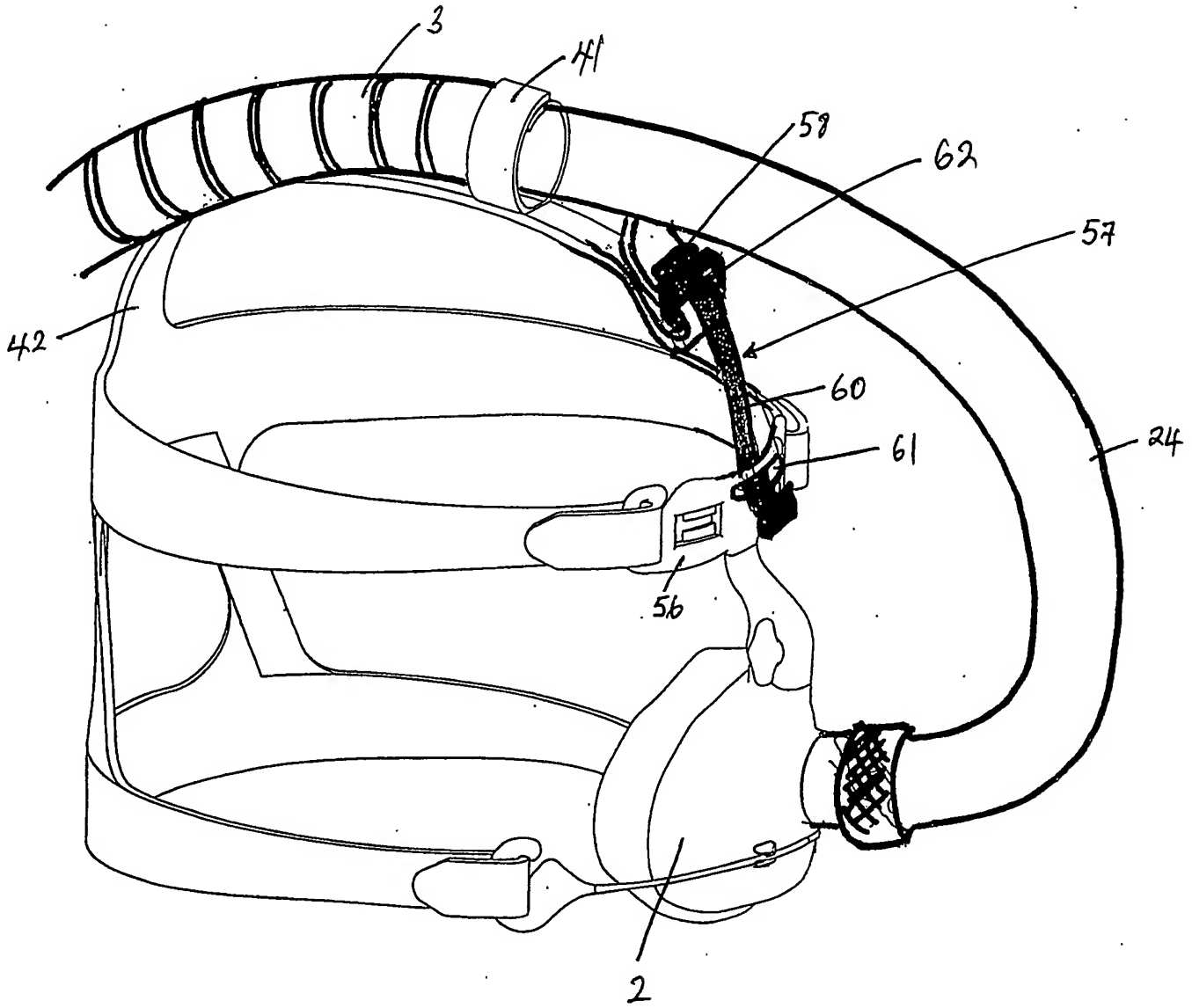

Figure 6

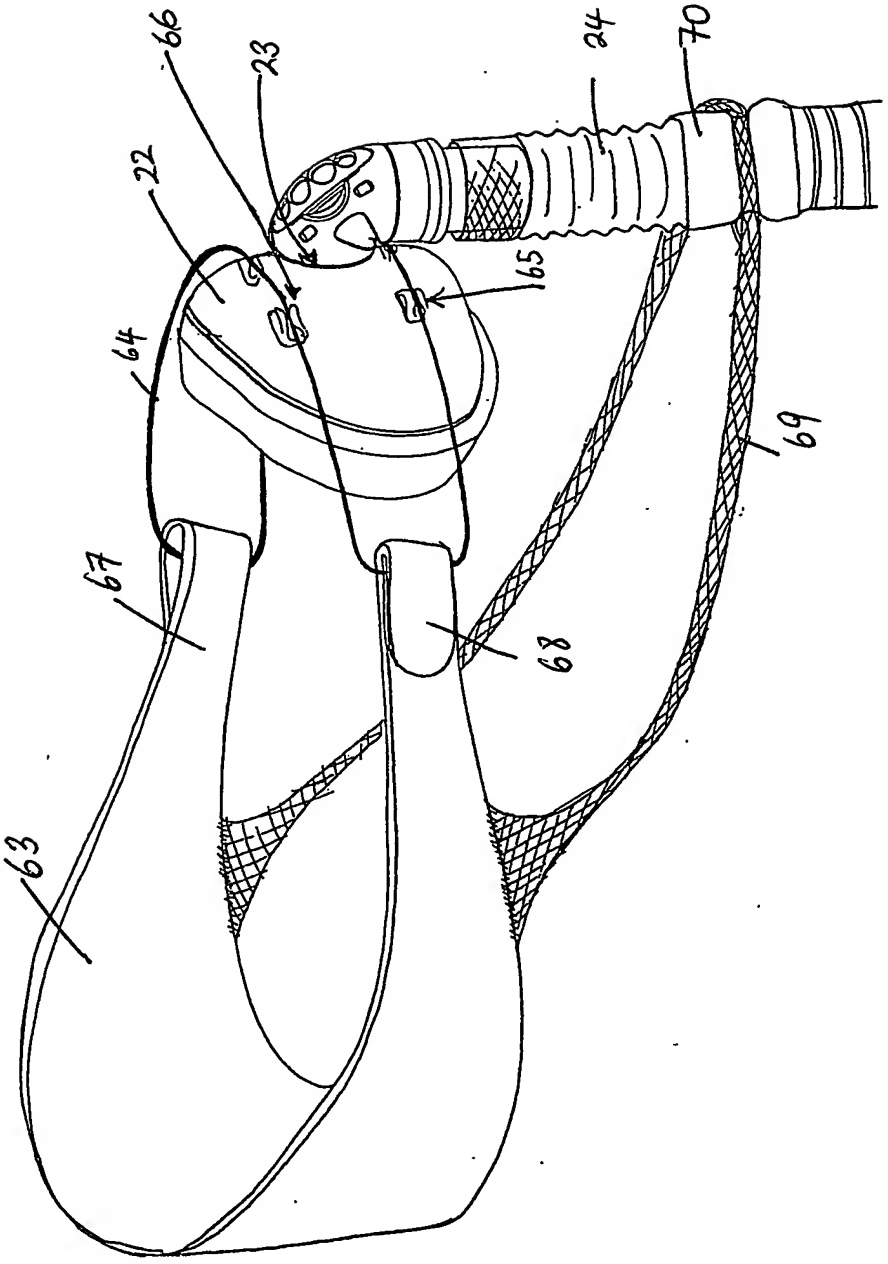

Figure 7

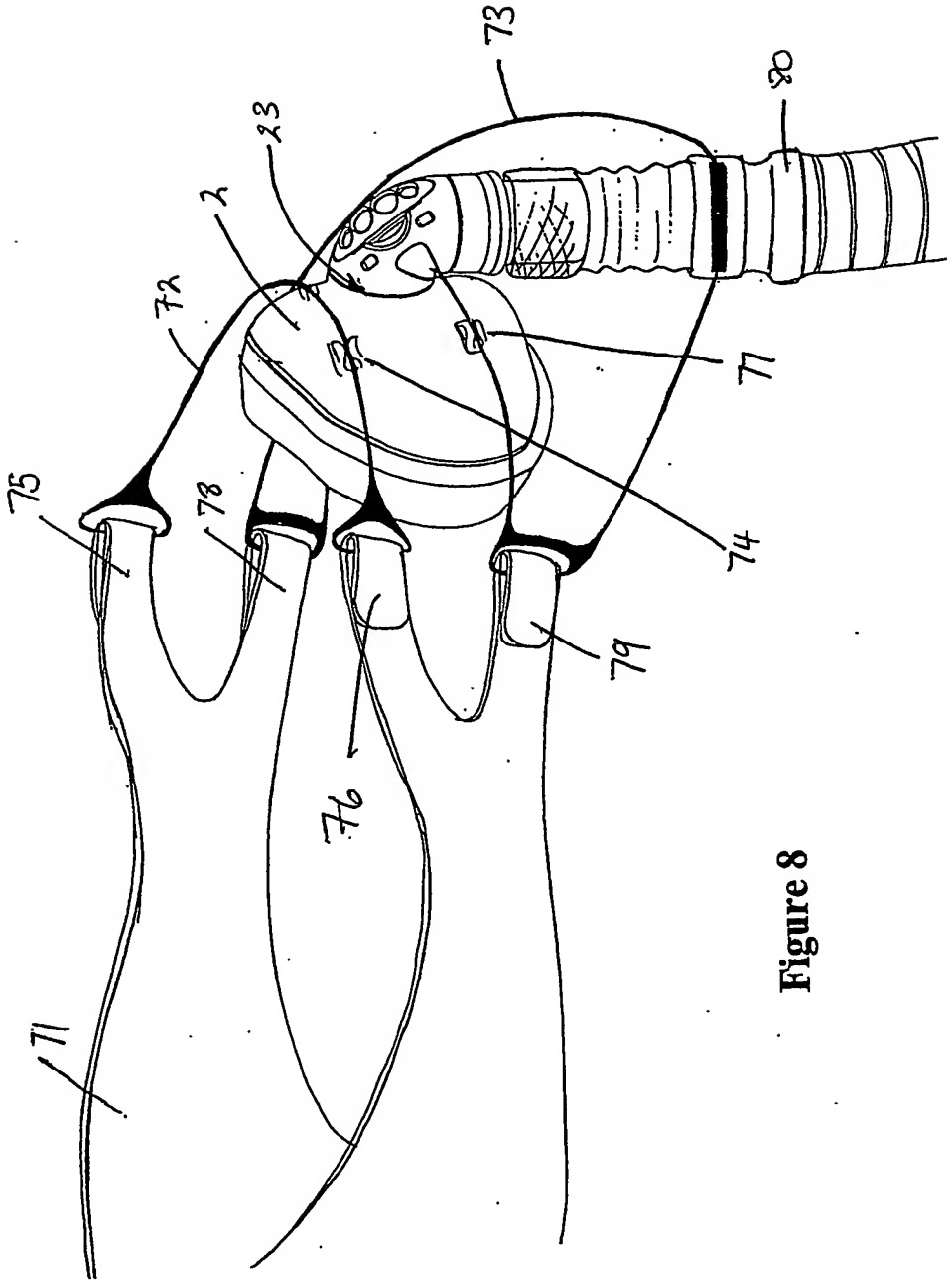

Figure 8

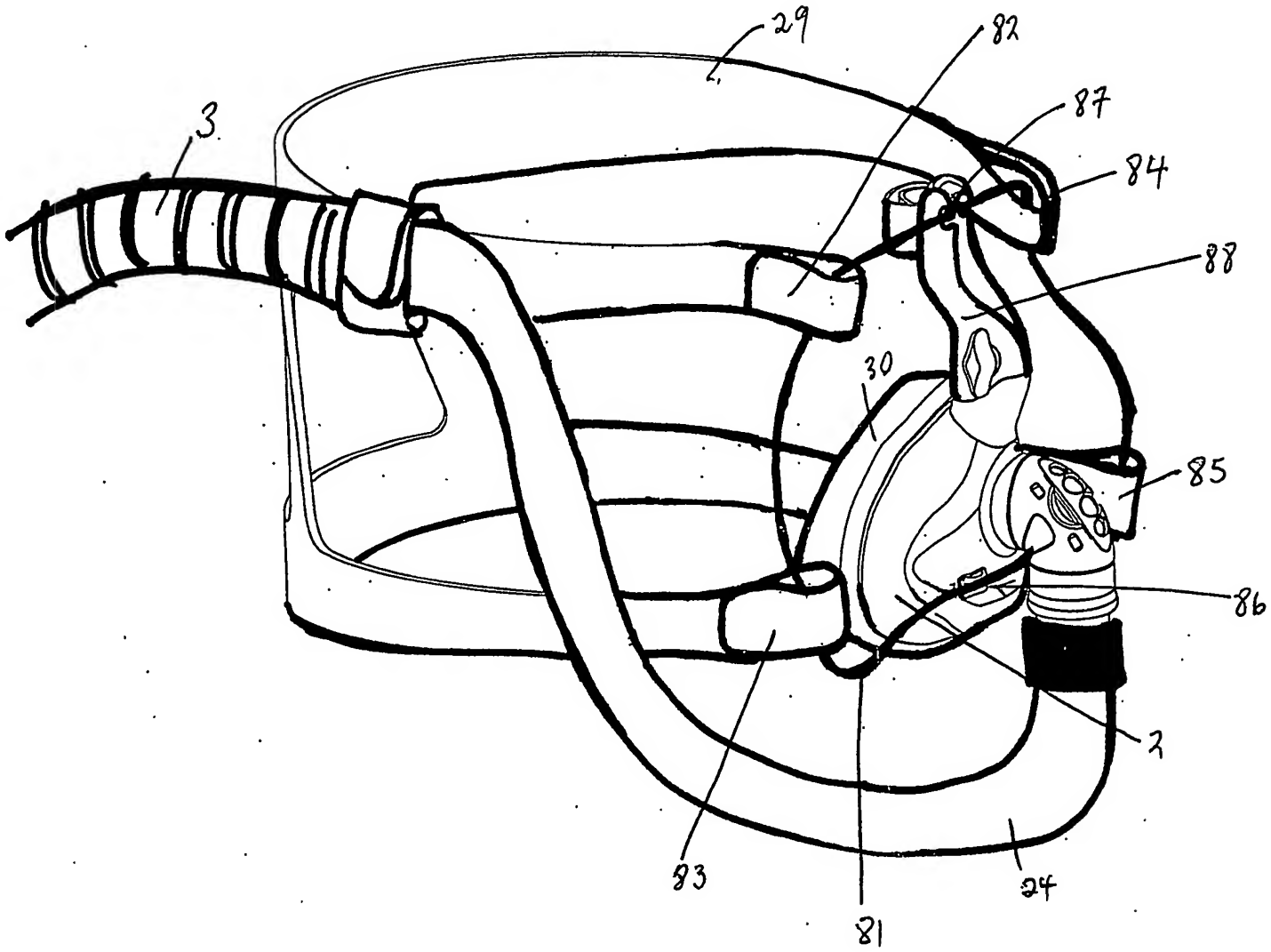

Figure 9

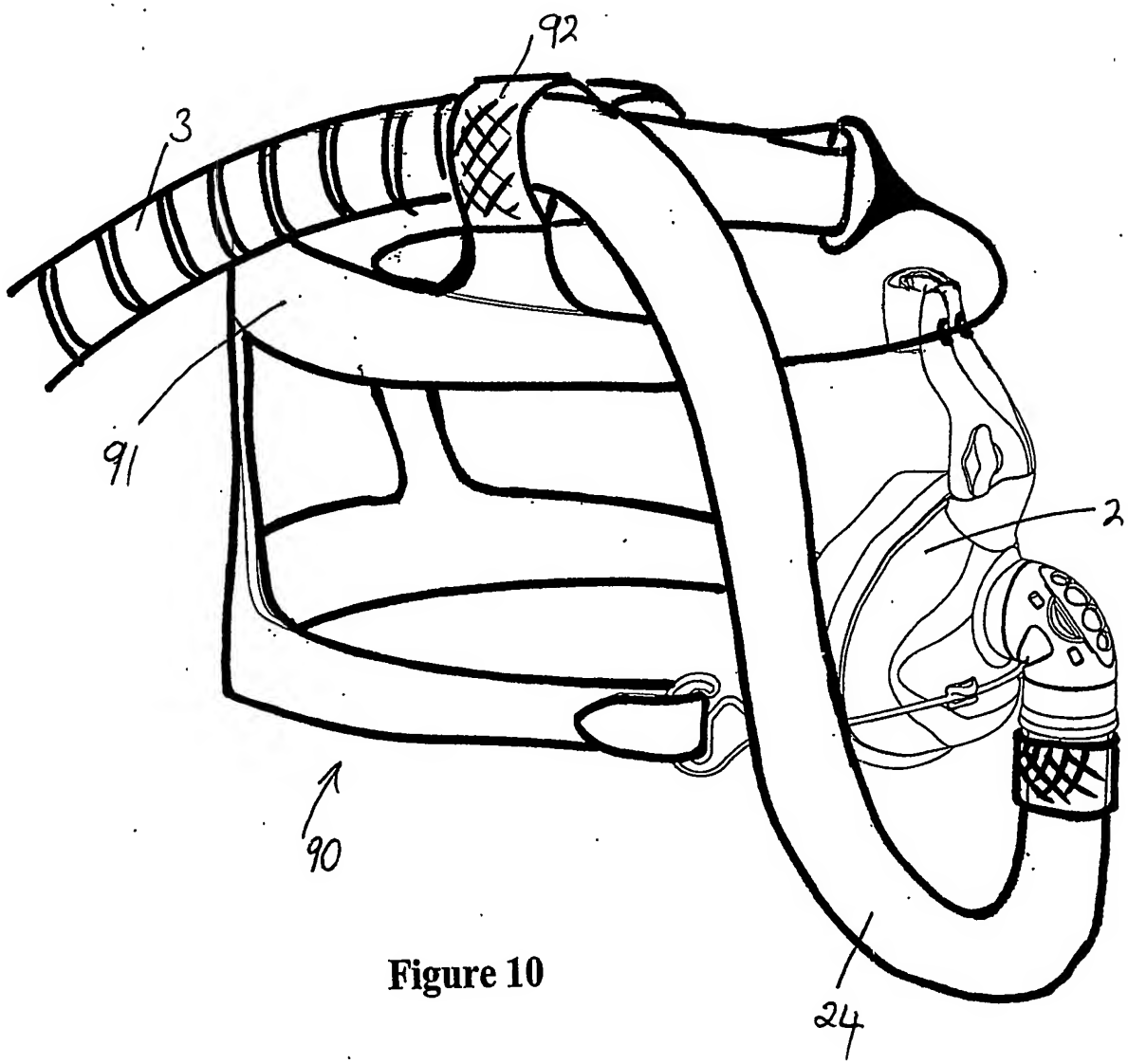

Figure 10

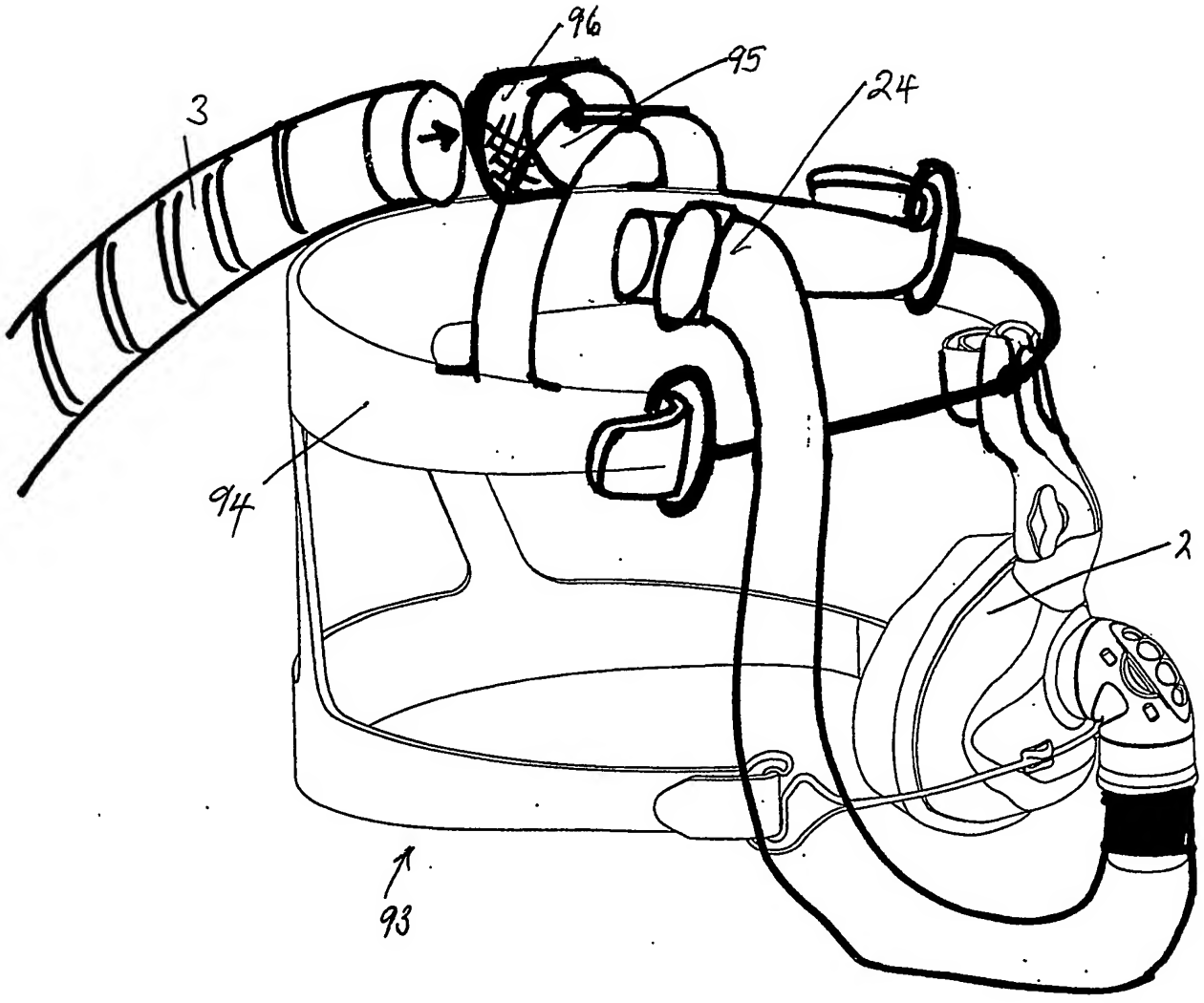

Figure 11

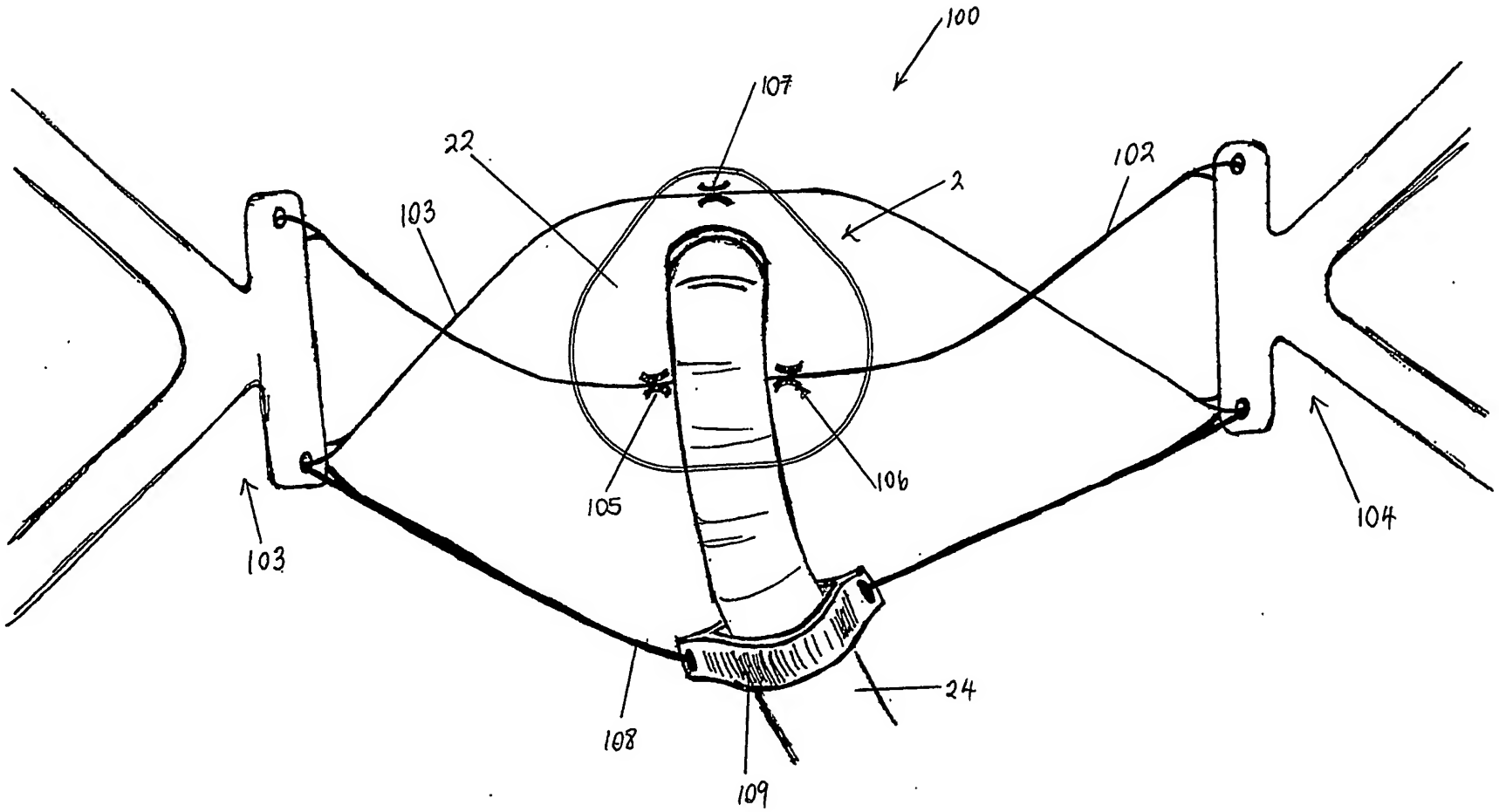

Figure 12